

DOCUMENT RESUME

ED 291 562

SE 048 894

TITLE Medical Research: National Research Service Awards for Research in Primary Medical Care. Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives.

INSTITUTION General Accounting Office, Washington, D.C.

REPORT NO GAO/HRD-87-20

PUB DATE 87

NOTE 34p.

AVAILABLE FROM U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20877 (first 5 copies free, additional copies \$2.00 each).

PUB TYPE Legal/Legislative/Regulatory Materials (090)

EDRS PRICE MF01/PC02 Plus Postage.

DESCRIPTORS \*Awards; Federal Aid; \*Government Publications; Grants; Incentives; Medical Education; \*Medical Research; \*Primary Health Care; Public Administration; Research; \*Science and Society; Science Education; Scientific Research

IDENTIFIERS \*General Accounting Office; \*National Institutes of Health

ABSTRACT

This report was written in response to questions from the Subcommittee on Health and the Environment concerning the implementation by the National Institutes of Health (NIH) of National Research Service Awards (NRSAs) in each of the fiscal years 1986, 1987, and 1988 made available for research in primary medical care. Discussions in this report include the definition of primary health care, justification of the 16 grants that NIH identified to the subcommittee, new solicitation required for grants, NRSAs for work in family medicine, the NIH determination of whether persons receiving NRSAs were likely to pursue careers relevant to primary medical research and legislative and administrative steps to be taken to assure compliance with the Public Health Service Act. The report lists and describes 16 NRSA recipients. Also included are comments from the Department of Health and Human Services. (CW)

\*\*\*\*\*  
 \* Reproductions supplied by EDRS are the best that can be made \*  
 \* from the original document. \*  
 \*\*\*\*\*

SE

United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

July 1987

# MEDICAL RESEARCH

## National Research Service Awards for Research in Primary Medical Care

ED 291562



U.S. DEPARTMENT OF EDUCATION  
Office of Educational Research and Improvement  
EDUCATIONAL RESOURCES INFORMATION  
CENTER (ERIC)

This document has been reproduced as received from the person or organization originating it.  
 Minor changes have been made to improve reproduction quality.

• Points of view or opinions stated in this document do not necessarily represent official OERI position or policy.

SE 048 894

---

Human Resources Division

B-224799

July 31, 1987

The Honorable Henry A. Waxman  
Chairman, Subcommittee on Health  
and the Environment  
Committee on Energy and Commerce  
House of Representatives

Dear Mr. Chairman:

This report responds to your August 15, 1986, letter, which raised several questions concerning implementation by the National Institutes of Health (NIH) of the first part of section 487(d)(3) of the Public Health Service (PHS) Act. This part requires that 1/2 of 1 percent of money appropriated for National Research Service Awards (NRSAs) in each of fiscal years 1986, 1987, and 1988 be made available for research in primary medical care. This section was added to the law in 1985 along with specific authorization for NRSAs for research in primary medical care. Previously the law referred only to biomedical and behavioral research. One-half of 1 percent of money appropriated for NRSAs amounted to \$1.2 million in fiscal year 1986 and \$1.3 million in fiscal year 1987.

We discussed implementation of section 487(d)(3) with officials of the Department of Health and Human Services (HHS), NIH, and the Health Resources and Services Administration (HRSA). We reviewed the criteria NIH used for identifying NRSAs in primary medical care and NIH documents describing 16 grants funded for \$2.1 million in fiscal year 1986, which NIH identified to your Subcommittee as examples of NRSAs complying with this section. We also discussed the work being done under the 16 grants with each grant's principal investigator.

Your questions and a summary of our findings are presented below. More detailed information on each question is provided in appendix I.

Was It Appropriate for NIH to Administer the First Part of Section 487(d)(3) of the PHS Act to the Exclusion of HRSA, and How Was This Decision Made?

It is not inappropriate for NIH to administer the first part of section 487(d)(3) of the PHS Act. Under the act the Secretary of HHS has the discretion to delegate administrative authority to any unit within HHS.

Section 487(a)(1) of the PHS Act authorizes HHS to provide NRSAs for biomedical and behavioral research and health services research including research in primary medical care. The Health Research Extension Act of 1985 added the specific requirement in section 487(d)(3) that money be set aside for research in primary medical care by persons affiliated with institutions that received grants and contracts under sections 780, 784, and 786 of the PHS Act.

NIH has historically administered NRSAs under section 487(a)(1); over \$200 million in NRSAs were awarded in fiscal year 1986. On April 11, 1986, HHS's deputy assistant secretary for Health Operations instructed NIH to transfer funds for administering the first part of section 487(d)(3) to HRSA. HRSA was selected because Health Operations staff associated primary care programs with HRSA. HRSA administers the Primary Health Care Block Grant Program. After NIH objected, the acting assistant secretary for Health met with headquarters-level HHS, NIH, and HRSA officials and decided on May 3, 1986, that NIH, not HRSA, would administer this part (a decision later confirmed by the deputy assistant secretary for Health Operations).

NIH objected to the proposed transfer of funds because NIH believed it was already funding NRSAs for research in primary medical care in excess of the 1/2 of 1 percent requirement of the section. NIH units identified to the Subcommittee a total of 151 NRSAs, funded for \$13.9 million in fiscal year 1986, that NIH believes are providing research related to primary care.

We have no basis to conclude that either NIH or HRSA is better suited to administer this provision.

Did NIH Adopt an Accepted Definition of Primary Medical Care for Purposes of Implementing Section 487(d)(3)?

NIH adopted a definition of primary medical care similar to that generally accepted by the medical profession. However, implementation of section 487(d)(3) does not depend simply on the meaning of primary medical care but rather research in primary medical care. Because neither the act nor its legislative history defines this term, HHS has reasonable discretion in determining what constitutes research in primary medical care.

While not establishing a precise definition of research in primary medical care, HHS has essentially adopted a position that any basic biomedical research that indirectly relates to primary medical care falls within the meaning of section 487(d)(3). As discussed below, we believe that this approach is unreasonable because it makes no distinction between biomedical research and research in primary medical care, a distinction the Congress clearly intended when it amended the law to add a new category of NRSAS for research in primary medical care that were not previously funded.

### Do the 16 Grants That NIH Identified for the Subcommittee Satisfy the Requirements of Section 487(d)(3)?

NIH identified for the Subcommittee 16 fiscal year 1986 grants, funded for \$2.1 million, as examples of NRSAS that NIH believed directly complied with the section 487(d)(3) requirement. We have serious reservations about whether all of the 16 grants NIH identified fall within the intended scope of research in primary medical care. Absent a clear indication of precisely what the Congress intended "research in primary medical care" to mean, and considering the lack of a fixed general understanding of this term in the medical community, we have no basis to conclude that the 16 grants do not satisfy the section 487(d)(3) requirement. In our view, however, the section established a requirement for NRSAS for research distinct from biomedical research, and HHS's interpretation of this section provides no reasonable explanation as to how the 16 grants it identified are distinct from basic biomedical research.

Our chief medical advisor believes that research in primary medical care is research relating to general health needs as opposed to more specialized research in medical care, generally referred to as biomedical research. Primary care focuses on the whole person, all of a person's health needs, including physical, psychological, and social. Primary care is the care provided on first contact with the health care system and on a continuing basis thereafter; it is provided by a primary care physician who has been defined by the medical profession as a general or family practitioner, general internist, general pediatrician, or obstetrician/gynecologist. In his opinion, the 16 grants awarded by NIH do not deal directly with the delivery of primary patient care, either initial or continued. Rather, they represent basic biomedical research in specialty areas of medicine.

In commenting on a draft of this report, HHS indicated that a precise definition of research in primary medical care is elusive. HHS stated that NIH clearly favors research in primary medical care and that NIH has complied with the letter and spirit of the law. HHS stated that to define

---

research in primary medical care as that which is “directly related to the delivery of health care,” as our chief medical advisor had suggested, is unduly restrictive. HHS believes that primary care has many aspects other than the actual delivery of care.

HHS noted that the 16 grants were narrowly chosen from those made to departments responsible for research training of pediatricians or internists and to entities that had received grants under sections 780, 784, or 786 of the act. For example, HHS maintains that the first NRSA listed in appendix II (Pediatric Oncology Training Program) meets the law’s requirements for research in primary medical care because it involves general pediatrics but that it does not meet our more restrictive requirement for being directly related to the delivery of health care.

Our conversations with the principal investigators of the grants revealed that there is no general agreement regarding the meaning of research in primary medical care. It is significant that 7 of the 16 principal investigators advised us that they did not believe their grants could be considered to be research in primary medical care (as they understood the term).

According to HHS, the best research training in primary care research may not be necessarily in primary care departments but in departments dealing with other disciplines. Biostatistics and epidemiology are considered to be essential tools for conducting research in primary medical care. Using a broader definition of research in primary care that emphasizes training in such disciplines, HHS asserted that more than \$1.8 million in fiscal year 1986 NRSAs made to such departments as preventive medicine and public health could be considered to meet the act’s requirement.

According to HHS, awards under the 1/2 of 1 percent set-aside would be to a very limited area of primary care if the restrictive definition is adopted, and nothing in the law or its legislative history indicates that the Congress intended such a restrictive definition. We believe that House and Conference Committee reports provide support for a logical inference that the Congress intended a very circumscribed field of research when it amended the existing law to include a new category of research in primary medical care and set aside a specific and very limited portion (1/2 of 1 percent) of NRSA appropriations. Specifically, the Conference report (Senate Report Number 99-157, at 81(1985)) states that:

"By placing a restriction on the provision of National Research Service Awards for individuals involved in family medicine, primary medical care and health research, the conferees recognize that during fiscal years 1986, 1987 and 1988 the pool of such persons is likely to be limited."

Our chief medical advisor agrees that the NIH grants indirectly relate to primary care because they may lead to better primary care treatment for disease and body dysfunction. However, in his opinion, the 16 grants represent basic biomedical research in specialty areas of medicine (e.g., pediatric oncology and hematology), including work dealing with specific diseases or body functions (e.g., cystic fibrosis and iron metabolism) and not with the direct delivery of primary medical care to patients. Using NIH's reasoning, any advance in the natural sciences that relates to medicine indirectly relates to primary medical care. Because this interpretation makes no distinction between biomedical research and research in primary medical care, it renders the Congress' legislative change meaningless and negates the purpose of specifically authorizing and setting aside funds for a category of NRSAs distinct from that previously authorized.

### Was a New Solicitation Required for Grants in Primary Care?

The law does not require that NIH solicit new proposals for research grants in primary medical care or that a solicitation be made of new recipients. Nothing in the law precludes NIH from using existing grantees to fulfill the requirements of section 487(d)(3). The 16 grants NIH identified to the Subcommittee were awarded between 1975 and 1982 and renewed on an annual basis.

On February 13, 1987, NIH issued a notice soliciting applications for fiscal year 1987 NRSAs in "research training in primary care disciplines." The notice did not define "research in primary medical care"; rather it listed examples of areas in which research projects would be appropriate. In commenting on a draft of this report, HHS stated that "adding a definition of primary care to the announcement . . . would have been redundant." According to HHS, the announcement was designed to recognize the broad diversity of interests considered relevant to research in primary care.

### Was NIH Required to Award NRSAs for Work in Family Medicine?

Section 487(d)(3) does not require that NRSAs be awarded for work in family medicine. It requires that awards be made to persons affiliated with hospitals, medical schools, and other public or private nonprofit institutions already receiving grants or contracts for establishing

departments of family medicine and for training programs in general internal medicine, general pediatrics, family medicine, and the general practice of dentistry. The law does not, however, require that NRSA grantees be affiliated with any particular units or departments of those institutions.

### To What Extent Did NIH Determine Whether Persons Receiving NRSAs Were Likely to Pursue Careers Relevant to Primary Medical Care Research?

NIH did not determine whether persons receiving training under NRSAs were likely to pursue careers in primary care research. An NIH official told us that NIH did not know the identity of individual trainees before the awards were made. Rather, NIH told us that NRSAs were awarded to institutions in consideration of their reputations for primary care research.

The law does not require that NIH determine whether persons receiving training under NRSAs are likely to pursue careers in research in primary care. Section 487(c) requires that persons receiving NRSAs engage in health research or teaching; NIH requires grantees to provide written assurance to this effect. An NIH official told us that NIH ascertains if trainees continue working in the same general research areas as the training grants by reviewing trainees' annual reports of payback service. Trainees are not required to perform payback service in the same specific research areas as their grants. Trainees who do not perform appropriate payback service are obligated to repay the dollar amounts of their grants.

### What Legislative or Administrative Steps Should Be Taken to Assure Compliance With Section 487(d)(3)?

HHS's comments indicate that NIH will continue to interpret the meaning of "research in primary medical care" so as to consider most biomedical research as meeting the requirements of section 487(d)(3). We continue to believe that HHS's interpretation of section 487(d)(3) is unreasonable because it does not clearly distinguish primary medical care research from biomedical research. Neither the law nor its legislative history is instructive in resolving this fundamental difference of opinion over what constitutes research in primary medical care, and there does not appear to be general agreement in the medical community over the meaning of the term.

### Matter for Consideration by the Congress

In light of the uncertainty over the meaning of "research in primary medical care," we suggest that the Congress consider amending the PHS Act to define what constitutes research in primary medical care for purposes of implementing section 487(d)(3).

---

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies to the Secretary of HHS, the Department's Inspector General, the Director of NIH, the Administrator of HRSA, the Director of the Office of Management and Budget, and other interested parties.

Sincerely yours,



Richard L. Fogel  
Assistant Comptroller General

# Contents

---

Letter	1
--------	---

---

Appendix I	10
National Research Service Awards for Research in Primary Medical Care	
Scope of Work	11
Was It Appropriate for NIH to Administer the First Part of Section 487(d)(3) of the PHS Act to the Exclusion of HRSA, and How Was This Decision Made?	11
Did NIH Adopt an Accepted Definition of Primary Medical Care for Purposes of Implementing Section 487(d)(3)?	13
Do the 16 Grants That NIH Identified for the Subcommittee Satisfy the Requirements of Section 487(d)(3)?	15
Was a New Solicitation Required for Grants in Primary Care?	19
Was NIH Required to Award NRSAs for Work in Family Medicine?	19
To What Extent Did NIH Determine Whether Persons Receiving NRSAs Were Likely to Pursue Careers Relevant to Primary Medical Care Research?	20
What Legislative or Administrative Steps Should Be Taken to Assure Compliance With Section 487(d)(3) of the PHS Act?	21
Matter for Consideration by the Congress	21

---

Appendix II	22
Awards Identified by NIH as Examples of NRSAs Fulfilling the Requirements of Section 487(d)(3)	
Pediatric Oncology Training Program	22
Pediatric Oncology Research Training Program	22
Hematology Career Training Program	22
Pediatric Pulmonary Disease and Cystic Fibrosis	22
Hematology Training Grant	23
Arthritis and Immunology	23
Training Program in Pediatric Allergy/ Immunology	23
Infectious Diseases in Pediatrics	23
Allergy and Clinical Immunology	24
Allergy and Immunology	24
Training Program in Inflammatory and Immunologic Diseases	24
Research Training in Mental Retardation	24
Graduate Research Training in Perinatology	24
Training in Perinatal Medicine	25

---

Research Training in Perinatal Medicine	25
Research Training in Perinatology	25

---

Appendix III Comments From the Department of Health and Human Services	26
---	----

---

**Abbreviations**

ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
NIH	National Institutes of Health
NRSA	National Research Service Award
PHS	Public Health Service

# National Research Service Awards for Research in Primary Medical Care

By an August 15, 1986, letter, the Chairman, Subcommittee on Health and the Environment, House Committee on Energy and Commerce, requested that we investigate implementation by the National Institutes of Health (NIH) of the first part of section 487(d)(3) of the Public Health Service (PHS) Act. The Chairman's letter raised seven questions concerning implementation of section 487(d)(3).

Section 487(d)(3) requires that 1/2 of 1 percent of money appropriated for National Research Service Awards (NRSAs) in each of fiscal years 1986, 1987, and 1988 be made available for research in primary medical care by persons affiliated with institutions that received grants or contracts under sections 780, 784, or 786 of the act. These sections authorize grants and contracts for establishing at hospitals, medical schools, and other public or private nonprofit institutions, departments of family medicine and training programs in general internal medicine, general pediatrics, family medicine, and the general practice of dentistry. The Health Resources and Services Administration (HRSA) is responsible for administering sections 780, 784, and 786. One-half of 1 percent of the money appropriated for NRSAs amounted to \$1.2 million in fiscal year 1986 and \$1.3 million in fiscal year 1987.

NRSAs consist of individual fellowship awards and institutional training grants for research and research training. NRSAs have historically been administered by NIH and awarded for training in biomedical and behavioral research. Before the Health Research Extension Act of 1985 amended the act, however, the provision of law that authorized NRSAs did not specifically list health services research or research in primary medical care as a separate area of NRSAs the Secretary of Health and Human Services was to award. The law referred to "biomedical and behavioral research." (See 42 U.S.C. 289 l-1 (1982), predecessor to section 487(a)(1), 42 U.S.C. 288(a)(1) (supp. III, 1985). The 1985 amendment added a specific reference to health services research and research in primary medical care. Thus, section 487(a)(1) of the PHS Act now authorizes NRSAs for "biomedical and behavioral research and health services research (including research in primary medical care)" (emphasis added).

The 1985 amendment also added to the law the specific requirement in section 487(d)(3) that 1/2 of 1 percent of the money appropriated for NRSAs be awarded for "research in primary medical care." The amendment, however, did not define this term. Nor is there a clear indication in the legislative history as to how the Congress intended this term to be construed. There is support in the legislative history for the logical

inference that by amending existing legislation to include a new category of research in primary medical care and to set aside a specific and very limited portion of NRSA appropriations, namely, 1/2 of 1 percent, the Congress intended to provide appropriations for research in areas distinct from the category "biomedical research" and not previously funded. The limited amount of funding (1/2 of 1 percent) suggests that the Congress may have had in mind a very circumscribed field of research.

## Scope of Work

We discussed implementation of section 487(d)(3) with officials of the Department of Health and Human Services (HHS), NIH, HRSA, and the National Center for Health Services Research and Technology Assessment. We obtained documents related to these officials' decisions on implementing this section. We reviewed the criteria used for identifying grants for research in primary medical care. For the 16 grants, funded for \$2.1 million in fiscal year 1986, which NIH identified to the Subcommittee as examples of NRSAs meeting the requirements of the first part of section 487(d)(3), we obtained from NIH copies of the notices of grant award, summary statements of NIH review committees, and excerpts from grant applications. Our chief medical advisor reviewed descriptions of the 16 grants contained in these documents to determine if research work under the grants constituted research in primary medical care. We also reviewed the legislative history of section 487(d)(3) and related legislation. In addition, we discussed the work being done under the 16 grants with each grant's principal investigator.

## Was It Appropriate for NIH to Administer the First Part of Section 487(d)(3) of the PHS Act to the Exclusion of HRSA, and How Was This Decision Made?

It is not inappropriate for NIH to administer the first part of section 487(d)(3). Under the act the Secretary of HHS has the discretion to delegate administrative authority to any unit within HHS. We have no basis to conclude that either NIH or HRSA is better suited to administer this provision. NIH has historically administered NRSAs under section 487(a)(1) of the act, and in fiscal year 1986 over \$200 million was appropriated for them. HRSA administers the Primary Care Block Grant Program.

The decision that NIH administer funds for primary care research authorized by section 487(d)(3) was made by the acting assistant secretary for Health on May 8, 1986, while meeting with top officials of NIH, HRSA, and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Section 487(a)(1) authorizes the Secretary of HHS to provide NRSAs for research and for training to undertake research. Since the law does not designate a specific unit within HHS to administer NRSAs, it is at

the Secretary's discretion to delegate the responsibility for implementation of this authority to any HHS unit. Furthermore, the legislative history of section 487(d)(3) does not indicate any particular HHS unit to which the Secretary is expected to delegate authority for awarding primary care research NRSAs. Consequently, the assistant secretary could decide that NIH administer funds authorized by section 487(d)(3).

By a February 6, 1986, memorandum, the acting administrator of HRSA requested concurrence from the deputy assistant secretary for Health Operations for HRSA to implement section 487(d)(3) by initiating a "new NRSA program for research in primary medical care." On April 11, 1986, the deputy assistant secretary issued a memorandum to NIH and ADAMHA directing them to transfer \$1.1 million to HRSA for implementing section 487(d)(3). A staff person in the deputy assistant secretary's office told us the Health Operations staff assumed that HRSA would administer the funds because one generally associates primary care programs with HRSA.

NIH's research training and research resources officer (who also functions as special assistant to the director of NIH) told us that NIH took exception to the proposed transfer of funds to HRSA because (1) NIH was already funding NRSAs for primary medical care research and (2) neither the law nor the Conference report on the law indicates that such awards must be made under the auspices of HRSA. However, this same official also commented to us that research, not primary care, is NIH's mission. In a July 26, 1986, internal NIH memorandum to the director, NIH's research training and research resources officer suggested that NIH invite the administrator of HRSA to discuss with NIH unit heads "what constitutes training in primary care and why NIH should support it." The memorandum stated that what HRSA staff have in mind is "health services research—not exactly NIH business."

On May 8, 1986, headquarters-level officials from HHS, NIH, and HRSA met to discuss implementation of section 487(d)(3). At that meeting, the acting assistant secretary for Health decided that the funding responsibility for primary medical care NRSAs originally proposed for transfer to HRSA would be retained by NIH and ADAMHA. The deputy assistant secretary for Health Operations confirmed this decision on May 27, 1986, by a memorandum to NIH, HRSA, and ADAMHA.

## Did NIH Adopt an Accepted Definition of Primary Medical Care for Purposes of Implementing Section 487(d)(3)?

NIH adopted a definition of primary medical care similar to that generally accepted by the medical profession. However, section 487(d)(3) requires that NIH fund NRSAS for “research in primary medical care” (emphasis added). The act itself does not define “research in primary medical care,” and the legislative history does not elaborate on the intended meaning of the term. Although a precise definition reflecting congressional intent is elusive, and HHS thus has reasonable discretion in its interpretation and application, we disagree with NIH’s interpretation because it does not distinguish between biomedical research and research in primary medical care.

While not proposing a precise definition of research in primary medical care, HHS suggests a broad definition that emphasizes research in basic tools of primary medical care research, i.e., epidemiology and biostatistics. HHS contends that primary medical care has many aspects other than the actual delivery of care and that the best research training in primary care may not be necessarily in primary care departments but in departments dealing with other disciplines (e.g., epidemiology and biostatistics). The essence of HHS’s position is that any basic biomedical research that indirectly relates to primary medical care falls within the meaning of section 487(d)(3).

We believe that this approach is unreasonable because it makes no distinction between biomedical research and research in primary medical care, a distinction the Congress clearly intended when it amended the law to add a new category of NRSAS for research in primary medical care distinct from the category “biomedical research” and not previously funded.

We disagree with HHS’s position because its interpretation encompasses virtually all biomedical research and negates the Congress’ purpose in setting aside a limited portion of funds appropriated, namely 1/2 of 1 percent, for NRSAS for research not previously included in the category of biomedical research. HHS’s interpretation of section 487(d)(3) renders the legislative changes meaningless.

In commenting on a draft of this report, HHS stated that NIH had adopted an appropriate definition of “research in primary care.” According to HHS, NIH staff sought assistance from the field in defining this term. HHS quotes someone it claims to be a widely respected professor of family and community medicine as writing

---

"It is certainly true that a definition of primary care research is hard to come by, something that is true of primary care itself and of other fields which are multidisciplinary, like health services research."

On March 4, 1986, NIH's research training and research resources officer sent a memorandum to all NIH units asking them to identify NRSAs they had made that "might meet the definition of research in primary medical care." The memorandum did not define the terms primary care physician, primary medical care, or research in primary medical care, or refer to any definitions of these terms. The memorandum referred to the requirements of section 487(d)(3). Attached to the memorandum was a copy of section 487(d)(3) and a list (obtained from HRSA) of institutions (e.g., medical schools and hospitals) that had received funds under sections 780, 784, and 786 of the PHS Act.

In response to the March 4, 1986, memorandum, NIH units identified 151 NRSAs, funded for \$13.9 million in fiscal year 1986, that NIH believes are related to primary care. The NIH units used various criteria to identify the 151 NRSAs. For example, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases stated that it considered a project related to primary care if it involved working with patients on a disease cared for by a primary care physician. The National Institute of Allergy and Infectious Diseases considered a project to be related to primary care if it was conducted (1) under the ultimate direction of a medical doctor or doctor of osteopathy, (2) in a medical school or hospital clinical unit, (3) in an area sufficiently broad to be related to the whole person, and (4) in medical areas in which primary care providers usually represent the point of entry of the patient into the health care system (general obstetrics/gynecology, general internal medicine, general pediatrics, and family practice).

On July 25, 1986, an NIH official notified the Subcommittee that NIH was making NRSAs in excess of the 1/2 of 1 percent required by section 487(d)(3). The NIH official provided a copy of the March 4, 1986, memorandum and responses to it from NIH units. The NIH official summarized this information and identified 16 grants funded for \$2.1 million in fiscal year 1986, which the official considered "only selected . . . examples directly responsive to the Congressional mandate" (emphasis added). All 16 of the NRSAs NIH identified were initiated between 1975 and 1982 with project periods lasting from 5 to 13 years and ending between 1987 and 1991. Each grant is renewed on an annual basis.

## Do the 16 Grants That NIH Identified for the Subcommittee Satisfy the Requirements of Section 487(d)(3)?

We have serious reservations about whether all of the 16 grants NIH identified fall within the intended scope of research in primary medical care. Due to the lack of a precise definition of the term in the law or legislative history and in the absence of general agreement in the medical community as to what constitutes research in primary medical care, we have no basis to conclude that the specific grants NIH identified do not satisfy the requirements of section 487(d)(3). However, we do not believe that HHS's interpretation and application of section 487(d)(3) is reasonable because it does not clearly distinguish primary medical care research from biomedical research or provide a reasonable explanation for how the 16 grants fall within the former rather than the latter category. In our view, section 487(d)(3) established a requirement for NRSAS for research distinct from biomedical research.

"Primary medical care," as that term is generally used in the medical profession, refers to the routine medical care and services people receive on first contact with the health care system for a particular health incident, i.e., prevention, maintenance, diagnosis, limited treatment, management of chronic problems, and referral.

Primary care is generally understood to focus on the whole person—all of a person's health care needs (i.e., physical, psychological, and social) and his or her first and continuing contact with health care providers and the community health care system. Primary care involves care to an unselected or unscreened population. The medical profession has defined a "primary care physician" as one who establishes a relationship with an individual or a family and provides continuing surveillance of their health care needs, comprehensive care for the acute and chronic disorders that the physician is qualified to care for, and access to the health care delivery system for those disorders requiring the services of other specialists. According to our chief medical advisor, the profession usually considers primary care physicians to be general practitioners and family practitioners, general pediatricians, general internists, and obstetricians/gynecologists. In addition, the PHS Act states that primary care "means general internal medicine, family medicine, and general pediatrics." Although the PHS Act does not specifically apply this definition to section 487(d)(3), it is nevertheless useful in determining the meaning of primary care research under that section.

Our chief medical advisor believes that research in primary medical care is research relating to general health needs as opposed to more specialized research in medical care, generally referred to as biomedical research. Research in primary medical care would, for example, deal

with topics or questions such as the following: (1) Can adverse health effects of stressful life events be prevented by interventions for families at the times they experience major life changes? (2) When is it appropriate to perform laparoscopy (visual examination of the abdomen) in young women with abdominal pain being seen in a primary care setting? (3) How adequate and acceptable is care provided in medically underserved areas? (4) To what extent is a community protected against poliomyelitis?

In his opinion, the 16 NRSAS identified by NIH for the Subcommittee as meeting the requirements of section 487(d)(3) of the PHS Act are for biomedical research on specific diseases and in specialty areas of medicine rather than primary care. The grants are for work in the specialty areas of allergy and immunology, arthritis and immunology, hematology, mental retardation, perinatology, and pediatric oncology and pulmonary disease. Most of the grants emphasize laboratory research on highly specialized topics.<sup>1</sup> A brief description of each of the 16 grants is contained in appendix II.

NIH staff believe that (1) work under the 16 grants is germane to primary care and (2) the grants are in compliance with the law because they were made to departments of pediatrics and internal medicine, both of which are considered to be primary care. NIH staff believe that such departments are "unequivocally training grounds for primary care."

An internal May 7, 1986, memorandum to NIH's director from NIH's research training and research resources officer (who also functions as a special assistant to the director) stated that she understood a principal author of section 487(d)(3) to have envisioned that under that section NRSAS be awarded to (university or medical school) departments of primary care, community health sciences, or family practice. The NIH official pointed out in the memorandum that this intent was not clearly spelled out in the law and that NIH was justified in maintaining its position of compliance with the law with NRSAS that are to departments in primary care fields. The memorandum also stated that NIH's purpose was to further research in the disciplines for which the 16 grants were awarded.

---

<sup>1</sup>For example, cellular immunology, cytogenetics, hemopoietic cell proliferation, insulin responsiveness of muscle in perfusion, lymphocyte biology, neurobiochemistry, and tumor virology.

In commenting on our draft report, HHS stated that NIH clearly favors research in primary medical care and has complied with the letter and spirit of the law. HHS stated that the definition offered by our chief medical advisor of research in primary medical care as that which is directly related to the delivery of health care is unduly restrictive and not supported by the letter or spirit of the law. HHS believes that primary care has many aspects other than the actual delivery of health care. Subsequent conversations with grant recipients revealed that there is no general agreement in the medical community regarding the meaning of research in primary medical care.

HHS noted that the 16 grants were narrowly chosen from those made to departments responsible for research training of pediatricians or internists and to entities that had received grants under sections 780, 784, or 786 of the act. For example, HHS maintains that the first NRSA listed in appendix II (Pediatric Oncology Training Program) meets the law's requirements for research in primary medical care because it involves general pediatrics but that it does not meet the more restrictive requirement for being directly related to the delivery of health care.

According to HHS, the best research training in primary care research may not be necessarily in primary care departments but in departments dealing with other disciplines. Biostatistics and epidemiology are considered to be essential tools for conducting research in primary medical care. Using a broader definition of research in primary care that emphasizes training in such tools, HHS asserted that more than \$1.8 million in fiscal year 1986 NRSAs to such departments as preventive medicine and public health could be considered to meet the act's requirement.

According to HHS, awards under the 1/2 of 1 percent set-aside would be to a very limited area of primary care if our restrictive application of the definition is adopted, and nothing in the law or its legislative history indicates that the Congress intended such a restrictive definition. We believe that House and Conference Committee reports provide support for a logical inference that the Congress intended a very circumscribed field of research when it amended the existing law to include a new category of research in primary medical care and set aside a specific and very limited portion (1/2 of 1 percent) of NRSA appropriations. Specifically, the Conference report (Senate Report 99-157, at 81(1985)) states that

"By placing a restriction on the provision of National Research Service Awards for individuals involved in family medicine, primary medical care and health research,

---

Appendix I  
National Research Service Awards for  
Research in Primary Medical Care

---

the conferees recognize that during fiscal years 1986, 1987 and 1988 the pool of such persons is likely to be limited.”

We talked to the principal investigators of the 16 grants NIH identified; 7 told us that their grants could not be considered to be research in primary medical care, and 9 thought that some or all of the research being done under their grants could be considered as such. Also, 9 of the principal investigators did not think that there was a general understanding of what constitutes research in primary medical care. One investigator said that research in primary medical care “could mean lots of different things to different people. The terms need to be more precise.” Another thought that his grant was appropriate for selection as research in primary medical care because some of the trainees do health services research. One principal investigator said that research in primary medical care is “in the eye of the beholder.”

Although responses to our inquiries of grant recipients suggest that there is no fixed general understanding of the term research in primary medical care, it is significant that seven stated that their grants were not research in primary care as they understood it.

We believe that using NIH’s reasoning, most biomedical research could be considered related to primary medical care and fall within the meaning of section 487(d)(3). The flaw in NIH’s approach is that it encompasses virtually all biomedical research and negates the Congress’ purpose of setting aside a limited portion of funds appropriated for NRSAs for research not previously included in the category of biomedical research.

HHS’s interpretation of section 487(d)(3) renders the legislative change meaningless. Any advance in the natural sciences that relates to medicine indirectly relates to primary medical care. To indulge HHS’s view would ignore settled rules of statutory construction that prohibit a construction that would render a new statute meaningless, and the presumption that by enacting an amending statute, the Congress intended some change in existing law (82 C.J.S. Statutes section 316(a) (1953)).

Moreover, the plain language of section 487(d)(3) does not refer to research “related to” primary medical care, nor is there any indication that the Congress intended the words “research in” to broaden the general understanding of “primary medical care.” In our view this section

established a requirement for NRSAs for research distinct from biomedical research, and HHS's interpretation of this section provides no reasonable explanation as to how the 16 grants it identified are distinct from basic biomedical research.

## Was a New Solicitation Required for Grants in Primary Care?

The law does not require that NIH solicit new proposals for research grants in primary medical care or that a solicitation be made of new recipients, i.e., persons who, although affiliated with institutions receiving grants or contracts under sections 780, 784, or 786 of the PHS Act, have not received NRSAs. Without a clear direction from the law, HHS is not required to make a new solicitation and is free to award NRSAs to eligible persons regardless of whether they had previously received an NRSA grant. Although the law was passed almost 2 months after fiscal year 1986 began (Nov. 1985), sufficient time was available to make a new solicitation.

According to HRSA officials, at a meeting on May 8, 1986, HHS, NIH, HRSA, and ADAMHA officials agreed to consider the requirement of section 487(d)(3) for NRSAs in primary medical care fulfilled for fiscal year 1986 through existing awards already made by NIH. Nothing in the statute precludes fulfilling the requirements of 487(d)(3) with existing awards.

On February 13, 1987, NIH issued a notice soliciting applications for NRSAs for "research training in primary care disciplines" related to the respective "mission areas" of NIH institutes. The notice did not define the term "research in primary medical care," but it did list examples of areas in which research projects would be appropriate. An NIH official told us that applications were due by May 1, 1987, and awards will be made by the close of fiscal year 1987. In commenting on our draft report, HHS stated that "adding a definition of primary care to the announcement . . . would have been redundant." According to HHS, the announcement was designed to recognize the broad diversity of interests considered relevant to research in primary care.

## Was NIH Required to Award NRSAs for Work in Family Medicine?

Section 487(d)(3) does not require that NRSAs be awarded for work in family medicine. The section requires that NRSAs in primary medical care be made to persons affiliated with institutions that have received funding under sections 780, 784, or 786 of the PHS Act. Sections 780 and 786 provide money to develop departments of family medicine and training programs in family medicine. Section 487(d)(3) does not require, however, that NRSA grantees be affiliated with any particular units or

departments of 780, 784, or 786 institutions. As a general rule, where a law contains a list of conditions, as does section 487(d)(3), the list is considered as comprehensive; i.e., the excluding of certain conditions is indicative of a legislative intent.

## To What Extent Did NIH Determine Whether Persons Receiving NRSAs Were Likely to Pursue Careers Relevant to Primary Medical Care Research?

NIH did not determine whether persons receiving training under NRSAs were likely to pursue careers in primary medical care research. An NIH official told us that when NRSAs are awarded to institutions as opposed to specific individuals, as were the 16, NIH does not know beforehand the identity of individual trainees. An NIH official told us that there is no way to determine in advance if trainees will pursue careers in primary care, but that awards are made in consideration of the reputations for primary care of the institutions and trainers involved.

Section 487(d)(3) does not require that NIH determine whether persons receiving NRSAs are likely to pursue careers in primary care. Section 487(c) requires that persons receiving NRSAs engage in health research or teaching. In accordance with this section, NIH requires individual trainees to complete PHS form 6031, NRSA Payback Agreement, when they enroll. This form requires written assurance that the trainees propose to do the following: engage in, on a full time, continuous basis, research or training to undertake research, within 2 years of termination of their NRSAs and for a period equal to that by which their NRSAs exceed 12 months. NIH requires trainees to complete annually a certification form describing their activities to fulfill the payback service requirements of section 487(c). An NIH official told us that NIH ascertains if trainees continue working in the same general research areas as the training grants by reviewing trainees' annual reports of their payback service. Trainees are not required to perform payback service in the same specific research areas as their grants. Teaching or research in the biological sciences would qualify, for example, as payback service for a grant dealing with reproductive biology. Trainees who do not perform appropriate payback service are obligated to repay the dollar amount of their grants.

---

**What Legislative or  
Administrative Steps  
Should Be Taken to  
Assure Compliance  
With Section 487(d)(3)  
of the PHS Act?**

HHS's comments on our draft report indicate that it will continue to interpret the meaning of "research in primary medical care" so as to consider most biomedical research as meeting the requirements of section 487(d)(3). We continue to believe that the research HHS refers to is primarily biomedical research in specialty areas of medicine. Although a precise definition reflecting congressional intent is elusive, and HHS thus has reasonable discretion in its interpretation and application, we believe that the approach taken by HHS is unreasonable because it makes no distinction between biomedical research and research in primary medical care, a distinction the Congress clearly intended. Neither the law nor its legislative history is instructive in resolving this fundamental difference of opinion over what constitutes research in primary medical care, and there does not appear to be general agreement in the medical community over the meaning of the term.

---

**Matter for  
Consideration by the  
Congress**

In light of this disagreement over the meaning of "research in primary medical care," we suggest that the Congress consider amending the PHS Act to define what constitutes research in primary medical care for purposes of implementing section 487(d)(3).

# Awards Identified by NIH as Examples of NRSAs Fulfilling the Requirements of Section 487(d)(3)

---

## Pediatric Oncology Training Program

Grantee Institution: University of Minnesota (Department of Pediatrics)

Description: This program provides multidisciplinary training consisting of both clinical and laboratory activity for postdoctoral trainees in the area of pediatric oncology. The program's goal is to produce clinicians with scholarly approaches to pediatric oncology, teachers, and clinical investigators/researchers. The program includes clinical rotation, formal course work, and a research project. Research facilities include specialized laboratories.<sup>1</sup>

---

## Pediatric Oncology Research Training Program

Grantee Institution: Fred Hutchinson Cancer Research Center, Seattle, Washington (Department of Pediatrics)

Description: This program consists of training in clinical aspects of pediatric oncology and related basic or laboratory research. Research opportunities are offered in specialized areas.<sup>2</sup>

---

## Hematology Career Training Program

Grantee Institution: Beth Israel Hospital (Harvard Medical School)

Description: This program trains M.D.s and Ph.D.s for careers in research and teaching related to blood and blood disorders. The central feature of the program is research training in the laboratory on highly specialized topics.<sup>3</sup>

---

## Pediatric Pulmonary Disease and Cystic Fibrosis

Grantee Institution: Case Western Reserve

Description: This multidisciplinary program for both predoctoral and postdoctoral physicians involves basic science laboratory work or clinical research augmented by formal course work.

---

<sup>1</sup>Such as blood cell culture, blood cell physiology, cellular biology, cytogenetics, tumor virology.

<sup>2</sup>These include immunology, transplantation pharmacology, and regulation of hematopoiesis.

<sup>3</sup>Including complement biology; certain host-tumor cell interactions and aspects of malignancy and tumor immunology; eosinophil and basophil physiology and metabolism; genetic studies related to immune response genes and the major histocompatibility complex; hemopoietic cell proliferation and myeloid cell differentiation; hemostasis, thrombosis, and platelet physiology; and iron transport and hemoglobin metabolism.

---

## Hematology Training Grant

Grantee Institution: Case Western Reserve University

Description: This training program is designed to prepare physicians or Ph.D. scientists for a career in academic medicine in hematology. Research training is available in specialized areas.<sup>4</sup>

---

## Arthritis and Immunology

Grantee Institution: University of North Carolina (Department of Medicine)

Description: This program provides predoctoral and postdoctoral trainees broad investigational experience in immunology and related disciplines, basic to the study of rheumatic diseases. <sup>5</sup> Trainees spend 20 percent or less of their time in clinical activities.

---

## Training Program in Pediatric Allergy/Immunology

Grantee Institution: University of California (Department of Pediatrics)

Description: This program in academic pediatric allergy and immunology trains pediatricians who are interested in teaching or research careers and want additional training in allergic or immunologic research. Research focuses on specific aspects of pediatric allergy and immunology.<sup>6</sup>

---

## Infectious Diseases in Pediatrics

Grantee Institution: University of Minnesota (Department of Pediatrics)

Description: This program prepares trainees for (1) research in biomedical sciences and (2) becoming faculty members, in academic departments of medical schools, who develop research laboratories for the study of infectious diseases, microbiology, and immunology.

---

<sup>4</sup>Including coagulation, fibrinolysis and granulocyte function, iron metabolism, and pyridine nucleotide metabolism.

<sup>5</sup>Other areas of interest include lymphocyte biology and immunoregulation, complement and cell surface structure and function, immunogenetics, and allergy.

<sup>6</sup>Including cellular immunity, developmental immunology, immediate hypersensitivity, and immunodeficiency.

---

## Allergy and Clinical Immunology

Grantee Institution: Duke University (Department of Pediatrics)

Description: This program trains physicians for medical school faculty positions as allergists, clinical immunologists, or both. The program strongly emphasizes research training with briefer periods of clinical teaching.

---

## Allergy and Immunology

Grantee Institution: Yale University (Department of Internal Medicine)

Description: This program trains physicians to teach, do research, and see patients in the areas of allergy and immunology. It includes formal course work, clinical training, and research.

---

## Training Program in Inflammatory and Immunologic Diseases

Grantee Institution: Duke University (Department of Medicine)

Description: The purpose of this program is to develop academically oriented physicians with clinical competence in both rheumatology and immunology as well as expertise in performing both basic and clinically related research.<sup>7</sup>

---

## Research Training in Mental Retardation

Grantee Institution: University of California (Clinical Department)

Description: This program trains predoctoral and postdoctoral candidates for careers in mental retardation research. The five major research groups are developmental biology, neurobiochemistry, neurophysiology, socio-behavioral, and access to mentally retarded subjects.

---

## Graduate Research Training in Perinatology

Grantee Institution: University of California (Department of Pediatrics)

Description: Provides multidisciplinary training in cardiovascular research, neonatology, and perinatology.

---

<sup>7</sup>Research focuses on cellular immunology, immunogenetics, and the basic mechanisms of inflammation and immune responsiveness as they pertain to autoimmune and other rheumatic diseases in which immunoregulation is impaired.

---

## Training in Perinatal Medicine

Grantee Institution: University of Colorado, Health Sciences Center  
(Department of Pediatrics)

Description: This program provides pediatricians and obstetricians with clinical training and laboratory experience.<sup>8</sup>

---

## Research Training in Perinatal Medicine

Grantee Institution: Yale University, School of Medicine (Department of Pediatrics)

Description: This program combines basic laboratory research with clinical research in developmental biology, cell biology, and biochemistry. It is designed for pediatricians and Ph.D.s committed to academic careers in perinatal medicine.<sup>9</sup>

---

## Research Training in Perinatology

Grantee Institution: University of Cincinnati (Department of Pediatrics)

Description: This program provides research and laboratory experience for M.D.s and Ph.D.s to prepare them for independent research in the broad spectrum of problems occurring in the perinatal period.

---

<sup>8</sup>Current investigations include airway reactivity and respiratory mechanics in children, maturation of bronchial reactivity in rabbits, and oxygenation of the rabbit uterus.

<sup>9</sup>Major areas for research include human clinical fetal genetic diagnosis utilizing ultrasound, fetoscopy, fetal monitoring, and fetal therapy; and neonatal clinical and animal experimental studies of cerebral blood flow.

# Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAY 28 1987

Mr. Richard L. Fogel  
Assistant Comptroller General  
U.S. General Accounting Office  
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report, "National Research Service Awards For Research In Primary Medical Care." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "R. Kusserow".

Richard P. Kusserow  
Inspector General

Enclosure

Appendix III  
Comments From the Department of Health  
and Human Services

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S (GAO) DRAFT REPORT, "NATIONAL RESEARCH SERVICE AWARDS FOR RESEARCH IN PRIMARY MEDICAL CARE," GAO/HRD-87-20BR, DATED APRIL 1987

GENERAL COMMENTS

A fundamental question that must be considered in any discussion of research training for future investigators concerns the scientific content of the research training program and the research environment in which it is provided. What research training is required to prepare investigators in primary care medicine?

General internal medicine and pediatrics have long recognized that primary medical care has an element of holistic medicine. Some of the best training for preparation of physicians to do research in internal medicine and pediatrics has been provided in the basic sciences. This is in keeping with the fundamental principle of the NIH research training program which is to assure the science base necessary to provide the future investigator with the knowledge, techniques and skills to conduct valid research. The best research training in primary care research may not be necessarily in primary care departments but in departments dealing with other disciplines. For example, one goes to basic departments of physiology or microbiology for certain types of clinical research training. One does not necessarily go to clinical departments. Biostatistics and epidemiology are considered to be the essential tools for conducting research in primary medical care. In Fiscal Year (FY) 1986, NIH supported more than \$1.8 million under the National Research Service Awards (NRSA) appropriation in epidemiology and biostatistics relevant to primary medical care.

NIH's investment in support for research in primary medical care is a well established activity. In a memorandum to the Assistant Secretary for Health dated June 14, 1983, the Director, NIH, stated that "in FY 1982, NIH awarded 39 million dollars to departments of Epidemiology, Community, Family or Preventive Medicine or some combination thereof. I do not believe the extent of NIH support is generally known." The memorandum goes on to add that "There might be some benefit from an intra-agency exchange of our various support activities to identify where good research may be going unfunded. I would be willing to have NIH represented at any PHS discussions designed to support research in primary care." The Director of NIH clearly favors research in primary medical care.

GAO ISSUE

Did NIH adopt an appropriate definition of research in primary medical care for purposes of implementing section 487(d)(3)?

NIH did not adopt a definition of research in primary medical care for the purpose of implementing 487(d)(3). NIH's research training and research resources officer sent a March 4, 1986 memorandum to all NIH units asking them to identify NRSAs they had made that "might meet the definition of research in primary medical care." The memorandum did not define "research in primary medical care" or make reference to any definitions of the term. The memorandum referred to the requirements of section 487(d)(3). Attached to the memorandum was a copy of section 487(d)(3) and a list (obtained from HRSA) of institutions (e.g., medical schools and hospitals) that had received funds under sections 780, 784, and 786 of the PHS Act.

DEPARTMENT COMMENTS

NIH did adopt an appropriate definition of research in primary medical care.

Much of the report centers around an appropriate definition of primary medical care. In discussions on research training programs in primary medical care disciplines with the Bureau, Institute and Division (BID) Directors and the Extramural Program Management Committee, NIH employed the following definition.

"The medical profession has defined a 'primary care physician' as one who establishes a relationship with an individual or a family and provides continuing surveillance of their health care needs, comprehensive care for the acute and chronic disorders which he/she is qualified to care for and access to the health care delivery system for those disorders requiring the services of other specialists. The profession generally considers primary care physicians to be general practitioners (GPs) and family practitioners (FPs), general pediatricians, general internists, and obstetricians/gynecologists."

This definition contains essentially the same elements which are referred to favorably on page 21 of the draft report.

Prior to adopting that definition, NIH staff had sought assistance from the field. The following is quoted from a letter written by a widely respected Professor of Family and Community Medicine in response to a request for a definition of primary care research. "It is certainly true that a definition of primary care research is hard to come by, something that is true of primary care itself and of other fields which are multidisciplinary, like health services research."

Now on p. 15.

The GAO discussion of definitions for the statutory terms "research in primary medical care," illustrates the problems with seeking to define these terms in a narrow mechanistic fashion. The GAO discussion begins reasonably enough, indicating that primary medical care, as generally used in the medical profession, "refers to the routine medical care and services people receive on first contact with the health care system for a particular health incident, i.e., prevention, maintenance, diagnosis, limited treatment, management of chronic problems, and referral." The GAO report further states that primary medical care is generally understood to focus on the whole person--all of a person's health care needs including physical, psychological, and social. The report also refers favorably to the PHS Act definition of primary medical care as meaning "general internal medicine, family medicine, and general pediatrics." These definitions are similar to the definition employed by NIH. However, as detailed below, the GAO applies these reasonable definitions in a manner that is unduly restrictive.

GAO ISSUE

Do the 16 grants that NIH identified for the Subcommittee satisfy the requirements of section 487(d)(3)?

Our findings are based on the law as written and the general understanding within the medical profession of what constitutes primary medical care. While we conclude that the 16 grants do not constitute research in primary medical care, an overall conclusion on whether HHS complied with the law cannot be made without analysis of the other 135 grants that NIH identified as providing such research. Should the remaining grants be ultimately found to be comparable to the 16 we reviewed, a sufficient basis could be established, in our opinion, for concluding that HHS had not complied with the first part of section 487(d)(3) of the PHS Act (from page 8 of the draft cover letter).

Primary care is generally understood to focus on the whole person--all of a person's health care needs (i.e., physical, psychological, and social) and his or her first and continuing contact with health care providers and the community health care system; primary care involves care to an unselected or unscreened population. According to our chief medical advisor, the profession usually considers primary care physicians to be general practitioners and family practitioners, general pediatricians, general internists, and obstetricians/gynecologists. In addition, the PHS Act states that primary care "means general internal medicine, family medicine, and general pediatrics." Although the PHS Act does not specifically apply this definition to section 487(d)(3), it is nevertheless useful in determining the meaning of primary care research under that section (from pages 20 and 21 of the draft report).

Now on p. 15.

DEPARTMENT COMMENTS

NIH has provided the required research training for preparing individuals to conduct research in primary medical care. Because NIH was sensitive to the general nature of the various definitions as to what constituted primary medical care, the examples of research training grants were narrowly chosen from those made to departments responsible for the research training of pediatricians or internists and to entities which received research training grants which had also "received grants or contracts under Section 780, 784, or 786" of the PHS Act.

Using a broader definition, one which emphasizes research training in the basic tools of primary medical care research, i.e., epidemiology and biostatistics, NIH can list research training awards made in FY 1986 to departments, such as preventive medicine, epidemiology and public health where the biostatistical and epidemiological nature of the research training is clear. The titles of these research training grants reflect such essential primary care concerns as nutrition, public health, aging, the prevention of cardiovascular disease, the epidemiology of bone diseases and cancer.

GAO concludes that the grants identified by NIH do not meet the definition, "because they do not deal directly with the delivery of primary patient care, either initial or continued." Delivery of care is not mentioned in either the statute or the broad definitions of primary care set forth in the GAO report. We believe that primary medical care has many aspects other than the actual delivery of care. In fact, this extremely limited definition is contradicted by the definitions cited earlier in the GAO report. One of those definitions refers to prevention, maintenance, diagnosis, limited treatment, management of chronic problems, and referral. Another definition cited favorably by the GAO refers to primary care as meaning general internal medicine, family medicine, and general pediatrics.

Although both of these definitions include elements relating to the delivery of health care, they certainly are not limited to the delivery of health care. For example, the first award identified by NIH (in Appendix I of the GAO report) as meeting the statutory requirement is a pediatric oncology training program that consists of training in the clinical aspects of pediatric oncology, and related basic or laboratory research. This program is clearly within the GAO definition of primary care as general internal medicine, family medicine, and general pediatrics. However, it does not appear to be within the GAO's unduly restrictive application of that definition to research training that is directly related to the delivery of health care. If this restrictive GAO interpretation is adopted, it would limit the one half of one

Appendix III  
Comments From the Department of Health  
and Human Services

Page 5

percent set-aside to a very limited area of primary care. We find nothing in the words of the statute or its legislative history to indicate that the Congress intended such a restrictive definition.

NIH believes it has complied with both the letter and the spirit of the law.

TECHNICAL COMMENTS

The memorandum from the NIH Research Training and Research Resources Officer paraphrased on page 4 of the transmittal letter, when viewed in context, describes the response to a request made to HRSA representatives for examples of what they considered primary care research. It stated that "those that rose readily to mind were without exception health services research-not exactly NIH business." The memorandum concluded with the suggestion that the Administrator of HRSA might be invited to discuss research training in primary care with the BID Directors. In subsequent discussions with the Administrator of HRSA, it was stated that epidemiology and biostatistics were the scientific disciplines basic to the conduct of research in primary medical care.

In addition to the information noted on page 19 of the draft report, it should be emphasized that adding a definition of primary care to the announcement of the availability of individual research fellowships in primary care disciplines would have been redundant. The announcement was designed to recognize the broad diversity of interests considered relevant to research in primary care. Discussions have begun with staff in the Bureau of Health Manpower Medical Division/HRSA, to develop review criteria. The announcement reflects NIH's continuing intention of being responsive, as well as responsible, in its administration of the NRSA research training program.

Now on p. 12.

---

Requests for copies of GAO reports should be sent to:

U.S. General Accounting Office  
Post Office Box 6015  
Gaithersburg, Maryland 20877

Telephone 202-275-6241

The first five copies of each report are free. Additional copies are \$2.00 each.

There is a 25% discount on orders for 100 or more copies mailed to a single address.

Orders must be prepaid by cash or by check or money order made out to the Superintendent of Documents.